UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC. ET AL, Plaintiffs, v. CELLTRION HEALTHCARE CO. LTD., ET AL., Defendants	)	C.A. No. 15-10698-MLW

MEMORANDUM AND ORDER

WOLF, D.J. September 29, 2016

This Memorandum is based on the transcript of the decision rendered orally on August 18, 2016, allowing defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira, Inc.'s, Motion For Summary Judgment Of Invalidity Of Claims 1, 3, 5, 6, 7 Of The '471 patent For Obviousness-Type Double Patenting In Light Of The Claims In The '195 And '272 patents (the "Reexam Motion"). The Memorandum adds citations and some text, and clarifies some language.

I. SUMMARY

Plaintiffs Janssen Biotech, Inc. and New York University, (collectively "Janssen"), are the holders of patents related to a biologic medication called Remicade, which is based on an antibody called infliximab. Plaintiffs allege that defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira, Inc. (collectively "Celltrion") have infringed these patents by filing

an abbreviated Biologic License Application for a product that is "biosimilar" to Remicade, which is named Inflectra.

Defendants have moved for summary judgment of invalidity on one of the patents at issue in this case, U.S. Patent Number 6,284,471 (the "'471 patent" or "'471"). They argue that claims 1, 3, 5, 6 and 7 of the '471 patent are invalid under the doctrine of obviousness-type double patenting over the claims in two now-expired patent previously held by plaintiffs, U.S. Patent Nos. 5,656,272 (the "'272 patent") and 5,698,195 (the "'195 patent").

For the reasons explained in this Memorandum, the Reexam Motion is being allowed. In summary, the court finds that the '471 patent is not protected by the safe harbor provided by 35 U.S.C. §121. The court also finds that the one-way test for obviousness-type double patenting, rather than the two-way test, applies in this case. As the plaintiffs concede for present purposes, the claims in the '471 are obvious in view of the earlier-issued claims in the '195 and '272. Assuming, without finding, that the two-way obviousness test should be applied, there may be disputed facts concerning whether the United States Patent and Trademark Office (the "PTO") was solely responsible for any delay that caused the '195 patent and '272 patent to issue before the '471 patent. However, any such disputes would not be material because the claims of the '471 patent are also obvious under the two-way test.

II. PROCEDURAL HISTORY

On February 19, 2016, defendants filed their initial Motion for Partial Summary Judgment on the '471 patent (Docket No. 127) (the "Gilead Motion"), which plaintiffs opposed. The court subsequently allowed defendants to file a second motion for summary judgment, the Reexam Motion, which plaintiffs also opposed.

On August 16, 2016, the court heard oral argument on the Reexam Motion. On August 18, 2016, the court issued an oral decision allowing the Reexam Motion. On August 19, 2016, the court issued an order summarizing the reasons for that decision. Like the August 18, 2016 transcript, this Memorandum provides a fuller explanation of those reasons.

III. APPLICABLE STANDARDS

A. SUMMARY JUDGMENT

Federal Rule of Civil Procedure 56(a) provides that the court "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." A factual dispute, therefore, precludes summary judgment if it is "material" and "genuine." See Anderson v. Liberty Lobby, 477 U.S. 242, 247-48 (1986).

A fact is "material" if, in light of the relevant substantive law, "it has the potential of determining the outcome of the litigation." Maymi v. Puerto Rico Ports Auth., 515 F.3d 20, 25 (1st Cir. 2008); Martinez-Rodriguez v. Guevara, 597 F.3d 414, 419

(1st Cir. 2010). "Only disputes over facts that might affect the outcome of the suit under the governing law properly preclude the entry of summary judgment." Anderson, 477 U.S. at 248.

The party moving for summary judgment "bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). However, the moving party's burden "may be discharged by 'showing' . . . that there is an absence of evidence to support the nonmoving party's case." Id. at 325. Summary judgment is, therefore, mandated "after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Id. at 322; Gorski v. New Hampshire Dep't of Corr., 290 F.3d 466, 475-76 (1st Cir. 2002); Smith v. Stratus Computer, Inc., 40 F.3d 11, 12 (1st Cir. 1994).

B. OBVIOUSNESS-TYPE DOUBLE PATENTING

"An issued patent is presumed valid and can only be proven invalid by clear and convincing evidence." Biogen Idec MA Inc. v. Trustees of Columbia Univ. in City of New York, 332 F. Supp. 2d 286, 296 (D. Mass. 2004) (citing 35 U.S.C. §282).

> [35 U.S.C. §101] precludes more than one patent on the same invention . . . . Section 101, however, only prohibits a second patent on subject matter identical to an earlier patent. Thus, applicants can evade this statutory requirement by drafting claims that vary slightly from the earlier patent.
>
> [Therefore, courts have] fashioned a doctrine of nonstatutory double patenting (also known as "obviousness-type" double patenting) to prevent issuance of a patent on claims that are nearly identical to claims in an earlier patent. This doctrine prevents an applicant from extending patent protection for an invention beyond the statutory term by claiming a slight variant.

Id. (quoting Geneva Pharm., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1377-78 (Fed. Cir. 2003)).

"'A later claim that is not patentably distinct from,' i.e., 'is obvious over[ ] or anticipated by,' an earlier claim is invalid for obviousness-type double patenting." Sun Pharm. Indus., Ltd. v. Eli Lilly & Co., 611 F.3d 1381, 1385 (Fed. Cir. 2010) (quoting Eli Lilly v. Barr Labs, 251 F.3d 955, 968 (Fed. Cir. 2001)). The doctrine of obviousness-type double patenting is primarily intended "to prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about." In re Hubbell, 709 F.3d 1140, 1145 (Fed. Cir. 2013) (quoting In re Van Ornum, 686 F.2d 937, 943 (C.C.P.A. 1982)). "The obviousness-type double patenting analysis involves two steps." Abbvie Inc. v. Mathilda and Terence Kennedy Institute of Rheumatology Trust, 764 F.3d 1366, 1374 (Fed Cir. 2014).

> "First, the court 'construes the claim[s] in the earlier patent and the claim [s] in the later patent and determines the differences.' Second, the court 'determines whether those differences render the claims patentably distinct.'" Sun Pharm. Indus., Ltd. v. Eli Lilly & Co., 611 F.3d 1381, 1385 (Fed. Cir. 2010) (alteration in original) (quoting Pfizer, Inc. v. Teva Pharm. USA, Inc., 518 F.3d 1353, 1363 (Fed. Cir. 2008)). "'A later claim that is not patentably distinct from,' i.e., 'is obvious over[ ] or anticipated by, 'an earlier claim is invalid for obviousness-type double patenting." Id. at 1385 (alteration in original) (quoting Eli Lilly, 251 F.3d at 968).

Id.

IV. FACTS

The following undisputed facts are among those that are relevant.

On February 2, 1993, plaintiffs filed U.S. Pat. App. No. 08/013,413 (the "'413 Application"), which is a parent application to the '471, '195, and '272 patents. See Pltfs' Resp. Stmnt ¶5. During prosecution of the '413 Application, the PTO Examiner issued a restriction requirement that, among other things, required plaintiffs to separate into different applications claims relating to the "chimeric antibodies" and claims relating to methods for using the antibodies to treat various conditions. See Pltfs' Resp. Stmnt ¶9.

On February 4, 1994, plaintiffs filed the application that resulted in the '471 patent, U.S. Pat. App. No. 08/192,093 (the "'093 Application"). See id. ¶6. The '093 Application was labeled a continuation-in-part of both the '413 Application and another

application because it added new material not present in the '413 Application. See id.; Pltfs' Stmnt. ¶¶90-95. The '471 patent was issued on September 4, 2001 and expires on September 4, 2018. See Pltfs' Resp. Stmnt ¶6.

On February 4, 1994, plaintiffs also filed the application that led to the '272 patent, U.S. Pat. App. No. 08/192/102 (the "'102 Application"). See id. ¶7. This application was also a continuation-in-part of the same applications as the '471 patent. See id. The '272 patent was issued on August 12, 1997 and expired on August 12, 2014. See id.

On October 18, 1994, plaintiffs filed the application that led to the '195 patent, U.S. Pat. App. No. 08/324,799. See id. ¶8. This application was a continuation-in-part of the '093 Application and two other applications. See id. The '195 patent was issued on December 16, 1997 and expired on December 16, 2014. See id.

The '471 patent claims a group of "chimeric antibodies." See Pltfs' Resp. Stmnt. ¶11. Claims 1, 3 5, 6, and 7 encompass the infliximab antibody, which is also called "cA2." See id. ¶13. The '471 patent does not claim infliximab specifically. See '471 patent col.20; see id. col.14 1.57-col.15 1.8. However, the specification describes the infliximab antibody and refers to it as a preferred embodiment of the invention. See id.

The '195 patent "claims methods of using cA2, i.e., infliximab, for treatment of rheumatoid arthritis." See Pltfs' Resp. Stmnt ¶19. In particular, Claim 6 recites "[a] method of treating rheumatoid arthritis in a human comprising administering to the human an effective TNF-inhibiting amount of chimeric anti-TNF anti[b]ody cA2." Id.; '195 patent col.108 ll.57-59.

The '272 patent "claims methods of using cA2, i.e., infliximab, for treatment of TNFα-mediated Crohn's disease." Id. ¶20. In particular, Claim 7 recites "[a] method of treating TNFα-mediated Crohn's disease in a human comprising administering to the human an effective TNF-inhibiting amount of chimeric anti-TNF antibody cA2." Id.; '272 patent col.98 ll.13-15.

V. DISCUSSION

Defendants appropriately framed the three questions of particular importance to the Reexam Motion. They are:

1. Are the plaintiffs entitled to the statutory 35 U.S.C. §121 safe harbor? The court finds plaintiffs are not.
2. If the §121 safe harbor is not applicable, which test for obviousness applies, the one-way test or the two-way test? The court finds that the one-way test applies in this case.
3. If the two-way test applies, is it proper to consider the '471 patent specification when conducting the analysis, and if so, is the '471 patent is invalid? The

court finds that it is proper to consider the specification and, when that is done, the '471 patent is invalid under the two-way test.

35 U.S.C. §121 establishes a safe harbor against double patenting invalidation for certain patents issued based on applications that are divisional of earlier applications. See Pfizer, Inc. v. Teva Pharm. USA, Inc., 518 F.3d 1353, 1359 (Fed. Cir. 2008). The statute provides that:

> If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application. The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention.

35 U.S.C. §121 (emphasis added).

The Federal Circuit applies "'a strict test' for application of section 121, '[g]iven the potential windfall [a] patent term extension could provide to a patentee.'" G.D. Searle LLC v. Lupin Pharm., Inc., 790 F.3d 1349, 1354 (Fed. Cir. 2015) (quoting Geneva, 349 F.3d at 1382). After filing an original parent application,

an applicant can file subsequent continuing applications that claim the priority date of the parent. See 37 CFR ¶1.78. There are multiple types of subsequent applications that may be filed, including divisional applications and continuations-in-part ("CIPs"). See id. The §121 safe harbor applies only to a patent derived from an application that is labeled "divisional."

In Pfizer, the Federal Circuit considered the question of whether the §121 safe harbor applied to a patent resulting from an application labeled "continuation-in-part" and not "divisional." The district court had held that the '068 patent, which was filed as a CIP, could not be invalidated for double patenting by the '165 patent because both "derived from applications filed in response to the restriction requirement made in the common parent application." 518 F.3d at 1358. The Federal Circuit reversed, holding that "the protection afforded by section 121 to applications (or patents issued therefrom) filed as a result of a restriction requirement is limited to divisional applications." Id. at 1362.

In reaching its conclusion, the Federal Circuit rejected the argument that "the terms 'divisional' and 'continuation-in-part' are merely labels used for administrative convenience" and that "the term 'divisional application' as it is used in section 121 refers broadly to any type of continuing application filed as a result of a restriction, regardless of whether it is labeled by

the PTO, for administrative purposes, as a divisional, a continuation, or a CIP." Id. at 1360. The court reviewed the legislative history of §121, noting that prior to its passage "no protection was afforded to patent applications filed as a result of a restriction requirement . . . and such applications were often rejected or held invalid on double patenting grounds." Id. at 1360-61. It explained that Congress recognized that it was unfair to require an applicant to split out inventions into separate applications and to use those compelled separate applications to invalidate resulting patents. See id. at 1361. However, the court noted that "[t]here is no suggestion [] in the legislative history of section 121 that the safe-harbor provision was, or needed to be, directed at anything but divisional applications" and that "[t]he difference between divisional applications and CIPs . . . was well known at the time of the 1952 Patent Act." Id. at 1361-62. The Federal Circuit concluded that "[i]f the drafters wanted to include CIPs within the protection afforded by section 121, they could have easily done so." Id. at 1362. It, therefore, held that "the protection afforded by Section 121 to applications or patents issued therefrom filed as a result of a restriction requirement is limited to divisional applications." Id.

In Amgen Inc. v. F. Hoffman-La Roche Ltd, 580 F.3d 1340, 1353 (Fed. Cir. 2009), the Federal Circuit stated that "[w]e are persuaded by the reasoning in Pfizer that that the §121 safe harbor

provision does not protect continuation applications or patents descending from only continuation applications. The statute on its face applies only to divisional applications, and a continuation application, like a continuation-in-part application, is not a divisional application." It concluded that "[w]e decline to construe 'divisional application' in §121 to encompass Amgen's properly filed, properly designated continuation applications." Id. at 1354.

In Amgen, the Federal Circuit explained that:

> unlike a continuation-in-part application, a continuation application can satisfy the definition of a "divisional application" in MPEP §201.06. That is because a continuation-in-part application adds subject matter not disclosed in the earlier application, see MPEP §201.08, whereas continuation and divisional applications are limited to subject matter disclosed in the earlier application, see MPEP §§ 201.06, 201.07. This distinction, however, does not justify departing from a strict application of the plain language of §121, which affords its benefits to "divisional application[s]." See 35 U.S.C. § 121[.]

Id. at 1353.

In the instant case, the '471 patent resulted from an application that was properly labeled a continuation-in-part. As indicated earlier, Janssen added new material to the application resulting in the '471 patent that did not appear in the earlier '413 Application. The application in Amgen was a continuation application that, like a divisional application, did not add any new material. Therefore, Amgen considered an application that was

more factually analogous to a divisional application than the continuation-in-part in this case and nevertheless held that the §121 safe harbor did not apply because the application was labeled as a continuation and not a divisional.

The court understands that the PTO is now reexamining the '471 patent and has allowed an amendment to label the relevant application a divisional. However, this action is not final and, therefore, is not effective. See 37 CFR ¶1.530(k). Moreover, if any such amendment becomes final, the application will not be one filed before the issuance of the other relevant patents as required by §121. This issue was addressed in G.D. Searle, supra. There the Federal Circuit wrote, with regard to the patents at issue:

> The '113 application [for the '068 patent] cannot be a divisional of the '594 application, despite being designated as such in the reissue patent, because it contains new matter that was not present in the '594 application. Simply deleting that new matter from the reissued patent does not retroactively alter the nature of the '113 application . . . . [B]ecause neither of those applications is a division of the original '594 application, the Section 121 safe harbor does not apply to the RE '048 patents.

790 F.3d at 1354-55.

It is undisputed that the application leading to the '471 patent was filed as a continuation-in-part and not denominated a divisional. Nevertheless, Janssen argues that this court has the discretion to deem the '471 patent application divisional.

However, Amgen addressed and rejected a comparable argument, stating:

> Amgen has not presented us with any persuasive reason as to why we should deem the '178 and '179 continuation applications divisional applications for purposes of §121. Amgen does not dispute that it denominated the '178 and '179 applications continuations, that it checked the continuation application box on the submitted form, or that its applications met the PTO's definition of a continuation application in MPEP §201.07. See Amgen's Br. 38, 42. Instead, Amgen argues that, because the '178 and '179 continuation applications could have been filed as divisional applications, we should treat them as such for purposes of § 121. While this argument convinced the district court to regard the '178 and '179 continuation applications as divisional applications, we are not likewise convinced. We decline to construe "divisional application" in §121 to encompass Amgen's properly filed, properly designated continuation applications.

See 580 F.3d at 1354. Essentially, Pfizer, Amgen, and Searle established a bright line rule that only patents resulting from applications filed as divisional are protected by the §121 safe harbor. This court does not have the discretion to deem the '471 patent application divisional. Therefore, the '471 patent is not protected by the §121 safe harbor.

Accordingly, the court must decide whether the one-way test for determining obviousness double patenting or the unusual two-way test should apply. The defendants argue for the one-way test. The plaintiffs assert the two-way test applies.

The one-way test analyzes whether the claims of a challenged patent are obvious in light of the claims of an earlier-issued

reference patent. See Hubbell, 709 F.3d at 1149. Under the two-way test, the court conducts the one-way analysis and also considers "whether the [reference] patent claims are obvious over the [challenged patent] claims." Id. at 1149. "Thus, when the two-way test applies, some claims may be allowed that would have been rejected under the one-way test." In re Berg, 140 F.3d 1428, 1432 (Fed. Cir. 1998).

"The two-way test . . . is 'a narrow exception to the general rule of the one-way test . . . .'" Hubbell, 709 F.3d at 1149 (quoting Berg, 140 F.3d at 1432). "[T]he two-way test is appropriate only in the 'unusual circumstance' where 'the PTO is solely responsible for the delay in causing the second-filed application to issue prior to the first.'" Id. (quoting Berg, 140 F.3d at 1437). The "typical scenario" to which the two-way test is applied is "'when a later-filed improvement patent issues before an earlier filed basic invention.'" Berg, 140 F.3d at 1434 (quoting In re Braat, 937 F.2d 589, 593 (Fed. Cir. 1991)) (emphasis in original). "[B]asic and improvement patents should not be penalized by the rate of progress of the applications through the PTO, a matter over which the applicant does not have complete control." Braat, 937 F.2d at 593.

At the August 16, 2016 hearing, plaintiffs' counsel confirmed, at least for the purposes of the Reexam Motion, that the '471 patent is obvious for double patenting over the '195 patent or the '272

patent if the one-way test applies. See Aug. 16, 2016 Tr. at 160. This conclusion is correct.

The court finds that the one-way test is the appropriate test. The applications for the '471 and '272 patents' were both filed on February 4, 1994. As indicated earlier, "the two-way test [is] appropriate . . . in the unusual circumstance that the PTO is solely responsible for the delay in causing the second-filed application to issue prior to the first." Berg, 140 F.3d at 1437; see also Hubbell, 709 F.3d at 1149; In re Fallaux, 564 F.3d 1313, 1316 (Fed. Cir. 2009). In this case, the PTO did not decide the applications in reverse order of filing because the applications for the '471 patent and the '272 patent were filed the same day. Therefore, the language of Berg, Hubbell and Fallaux indicates that the two-way patenting test does not apply to those two patents at least.

The PTO's Manual of Patent Examining Procedures (the "MPEP") is consistent with this conclusion. It states that "[i]f both applications are filed on the same day, only a one-way determination of distinctness is needed in resolving the issue of double patenting." MPEP §804.II(B)(2)(b). The MPEP cites Berg for this proposition. Plaintiffs, however, argue that Berg does not control this question.

The court agrees that Berg does not control because the issue, although presented, was not decided. In Berg, the inventor chose

to file two applications simultaneously for inventions the Federal Circuit found could have been included in a single application. See 140 F.3d at 1433. The court held that "simultaneously filing two separate applications that could have been filed as one application disqualifies the applicant from the two-way test." Id. at 1435. The Federal Circuit neither accepted nor rejected the PTO's other reason for finding the two-way test inapplicable--the fact that the applications at issue were filed on the same day. See id.

In the instant case, in 1993, Janssen originally filed all of its claims in a single application. The PTO required that it file multiple applications, two of which were filed on the same day, February 4, 1994, as continuation-in-part applications. The third continuation-in-part application was filed on October 4, 1994. In Berg, the Federal Circuit addressed what should be done to avoid obviousness-type double patenting if the PTO determines that claims in a single application belong in multiple applications. It wrote that the inventor should file one or more divisional applications, which would be protected by the §121 safe harbor provision. See id. at 1435 to 36. Janssen did not do this.

In Berg, the applicant could have filed a single application. See Berg, 140 F.3d at 1435. Instead, it was "viewed as taking a calculated risk that, by simultaneously filing two separate applications, it might gain the advantage of a quickly issued narrow

patent and also the advantage of a broader application which took longer to issue as a patent but consequently had a later application date." Id. The Federal Circuit held that this disqualified Berg from receiving the benefit of the two-way test because "[e]ffectively extending the patent term [] is precisely the result that the doctrine of obviousness-type double patenting was created to prevent." Id.

In the instant case, the PTO's restriction requirement compelled the filing of a separate application for what became the '471 patent. However, plaintiff could have filed a divisional application. Instead, it chose to add new material to the application, perhaps strengthening the case for the issuance of the patent or making the PTO review process more protracted. This new application was properly labeled a continuation-in-part. Although plaintiffs conduct occurred before Berg was decided, the court concludes that they too took a calculated risk that disqualifies them from being eligible for employment of the two-way test.

As discussed earlier, the applications for the '272 patent and the '471 patent were filed on the same day. The '272 patent for a method of treating Crohn's disease with infliximab issued in 1997. The broader '471 genus patent issued in 2001. Janssen began receiving patent protection in 1997 under the '272 patent. If the obviousness double patenting doctrine were not applied here, Janssen's right to exclude the public from practicing the '272

patent would, in effect, be extended to 2018. As explained earlier, the primary justification for obviousness double patenting is "to prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about." Hubbell, 709 F.3d at 1145. It is appropriate to apply this principle to find, as the PTO would according to the MPEP, that the usual one-way test is applicable in this case. As indicated earlier, plaintiffs concede for present purposes that the '471 patent is invalid for obviousness-type double patenting under this test.

However, in the interest of completeness, the court is also addressing the issue of how the two-way obviousness test would operate if it were applicable in this case. As indicated earlier, "the two-way test is appropriate only in the unusual circumstance that the PTO was solely responsible for the delay in causing the second-filed application to issue prior to the first." Berg, 140 F.3d at 1437. The Federal Circuit wrote in Hubbell that "obviousness-type double patenting is a question of law we review de novo. We review the Board's factual findings for substantial evidence." 709 F.3d at 1145. In the context of this case, as this statement indicates, there may be a genuine factual dispute concerning whether the PTO was solely responsible for the delay that caused the earlier-filed '471 to issue after the later-filed '195. See Engineered Prod. Co. v. Donaldson Co., 225 F. Supp. 2d

1069, 1089 (N.D. Iowa 2002), aff'd in part, rev'd in part and remanded, 147 F. App'x 979 (Fed. Cir. 2005).

If there was a genuine dispute concerning a fact that is material, the court would have a jury decide the disputed issue of whether the PTO was solely responsible for the delay that caused the later-filed application to result in the patent issued first. The jury's decision would determine whether the two-way test applies. Plaintiffs contend there are disputed facts and, therefore, summary judgment is not proper concerning the two-way test. However, even assuming without finding that whether the PTO was solely responsible for the delay is in genuine dispute, that fact is not material to the outcome of this motion for summary judgment because the plaintiffs would fail the two-way test.

With regard to the two-way test, one of the primary contested issues is whether the court may consider the '471 patent specification when deciding the second prong of the two-way test- - whether the claims of the '195 and '272 patents are obvious in light of the '471 patent. The court finds that the '471 patent specification may be considered.

"It is [] well settled that [the court] may look to a reference patent's disclosures of utility to determine the question of obviousness." Abbvie, 764 F.3d at 1381. "The Federal Circuit has repeatedly approved examination of the disclosed

utility of the invention claimed in an earlier patent to address the question of obviousness." Id. at 1382.

The Federal Circuit held in Sun that:

> the specification's disclosure may be used to determine whether a claim 'merely define[s] an obvious variation of what is earlier disclosed and claimed,' 'to learn the meaning of [claim] terms,' and to 'interpret [ ] the coverage of [a] claim.' . . . [W]here a patent features a claim directed to a compound, a court must consider the specification because the disclosed uses of the compound affect the scope of the claim for obviousness-type double patenting purposes.

611 F.3d at 1387 (citations omitted). In the instant case, it is undisputed that the '471 patent is to a compound. Therefore, it is appropriate to consider the specification.

Plaintiffs argue that Sun is restricted to circumstances in which the claims of the patent do not refer to a utility of the invention. However, the Federal Circuit in Sun rejected essentially the same argument, stating that "the holding of Geneva and Pfizer, that a 'claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use,' extends to any and all such uses disclosed in the specification of the earlier patent." Id. at 1385-86.

Here, the '471 patent's specification discloses the utility for the claimed genus of compounds, and the infliximab antibody in particular, for treating Crohn's disease and rheumatoid arthritis. The specification describes the infliximab antibody, see '471

patent col.20, even including it as a preferred embodiment of an invention, see id. col.14 l.57-col.15 l.8. It also discusses the utility of this class of compounds in treating various conditions, including rheumatoid arthritis and TNFα-mediated Crohn's disease. See Pltfs' Resp. Stmnt ¶21; '471 patent col.33 l.52 to col.35 l.3. The specification also describes two studies where the infliximab antibody was used to treat rheumatoid arthritis and Crohn's disease. See Pltfs' Reply Resp. Stmnt ¶¶36-37; '471 patent at col.58 l.23 to col.65 l.67, col.66 l.20 to col.68 l.20. Therefore, the '471 patent specification expressly describes the methods of using the infliximab antibody to treat Crohn's disease and rheumatoid arthritis that are claims in the '195 and '272 patents.

The Federal Circuit stated in Geneva Pharm., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1385-86 (Fed. Cir. 2003), that a "claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use." Therefore, the '195 and '272 patents are obvious in light of the '471 patent under the second prong of the two-way obviousness test. As both prongs of the two-way obviousness test are satisfied, claims 1, 3, 5, 6, and 7 of the '471 patent would be invalid for obviousness-type double patenting if the two-way test were applicable.

Plaintiffs argue that, even if the court considers the '471 patent specification, disputed facts bar the court from concluding

on the motion for summary judgment that the '195 and '272 claims are obvious in light of the '471 patent. They assert that the '471 patent claims recited a genus of antibodies, not the infliximab antibody in particular. In contrast, the '195 and '272 patents recite methods for using the infliximab antibody itself. They contend that it is a disputed fact whether the methods of using a specific species in the genus are rendered obvious in light of the genus. This argument ignores the fact that the '471 patent specification expressly describes using the infliximab antibody itself to treat Crohn's disease and rheumatoid arthritis. The '471 does not limit its discussion to the more general question of using the genus to treat these diseases. Therefore, plaintiffs' argument that obviousness-type double patenting cannot be decided on a motion for summary judgment is not meritorious.

In summary, the court finds as follows. The '471 patent is not protected by the §121 safe harbor. The one-way test is applicable and, as plaintiffs concede for present purposes, the '471 patent fails that test. The court also finds that even if the two-way test were applicable, the '471 patent would be invalid for obviousness-type double patenting. Therefore, defendants' motion for summary judgment is being allowed.

VI. ORDER

In view of the foregoing, as previously ordered on August 19, 2016, Defendants' Motion For Summary Judgment Of Invalidity Of

Claims 1, 3, 5, 6, 7 Of The '471 patent For Obviousness-Type Double Patenting In Light Of The Claims In The '195 And '272 patents (Docket No. 176) is ALLOWED.

UNITED STATES DISTRICT JUDGE